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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/784,336	02/23/2004	Glen E. Jorgensen	47168-00158USD1	8712

30223 7590 03/27/2007  
JENKENS & GILCHRIST, P.C.  
225 WEST WASHINGTON  
SUITE 2600  
CHICAGO, IL 60606

EXAMINER
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CHAPMAN, GINGER T

ART UNIT	PAPER NUMBER
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3761

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/27/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/784,336

Applicant(s)

JORGENSEN ET AL.

Examiner

Ginger T. Chapman

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 4,5 and 8-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 11 is/are allowed.
- 6) ☒ Claim(s) 4,5,8-10 and 12-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of the claims***

By way of Applicants' amendment filed 4 October 2006: claims 13-16 are added; claims 4, 5, 8-16 are pending in the application.

### ***Specification***

The objection to the specification made of record in the previous Office action is withdrawn due to Applicants amendment filed 4 October 2006.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 4, 5, 8-10, 12-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over McEwen et al. (4,828,716) in view of Kelly et al. (6,074,883).

With regard to claims 4-5, McEwen discloses a method wherein blood is collected from a patient using a needle set and collected or transferred into a container and tubing is connected to the container for delivery and withdrawal of components. The container has a piston (closure 16) that moves as a result of the centrifugation to separate the blood into its components. The container is placed within a centrifuge for a spin to separate the blood into its components. McEwen teaches that the separated serum is removed or withdrawn after separating and is decanted (i.e. is expelled into a waste container). See figures 1a-1g; col. 7, line 28 to col. 9, line

Art Unit: 3761

49. McEwen also teaches that the components may be further separated by centrifugation until desired separation of components is achieved. Col. 14, lines 43-51.

McEwen et al disclose the method substantially as claimed except for disclosing specifically the following: that the separated red blood cells are expelled into a waste bag; the step of attaching a hollow plunger rod with a port to displace separated platelet-poor plasma by moving the plunger toward the first port; a "soft" and "heavy" spin; or that the collection container contains a small amount of anti-coagulant.

Kelly discloses a method and apparatus for using a disposable blood tube holder wherein the apparatus includes a hollow plunger rod with a port to separate components. The device of Kelly includes a container that includes a connection means to attach a plunger (102) that has a hollow plunger rod (118) for removing separated components. At the time of the invention, it would have been obvious to one of ordinary skill in the art to have modified the apparatus of McEwen to include a hollow plunger rod to easily remove separated plasma without disturbing the separated cells in the container.

With respect to claims 8 and 9, McEwen teaches that the centrifuge has a motor and control device that can control the speed as desired. Therefore, a "soft" and "heavy" spin may be achieved by the method of McEwen. Since McEwen teaches that separated serum is removed or withdrawn after separating and is decanted (i.e. is expelled into a waste container) it would be an obvious step in such a method to choose to decant separated red blood cells into a bag to one having ordinary skill in the art. If red blood cells are not the desired end product of the method, there would be no reason to keep them and decanting or expelling them into a waste container is

Art Unit: 3761

standard operating procedure in medical laboratories. With respect to using a waste bag, a container is an equivalent to a bag.

With regard to claims 10, 13 and 14, it would have been obvious to perform the displacing step either automatically or manually since it has been held that broadly providing a mechanical or automatic means to replace manual activity which has accomplished the same result involves only routine skill in the art, *In re Venner*, 120 USPQ 192.

Applicant has provided no criticality for the step to be performed manually or automatically, the specification contains no disclosure of either the critical nature of the claim limitations nor any unexpected results arising therefrom, and that as such the limitations were arbitrary and therefore obvious. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with performing the step either manually or automatically because both perform the same function of displacing the cells and plasma, and in the instant case substitution of equivalent methods requires no express motivation, as long as the prior art recognizes equivalency, *In re Fount* 213 USPQ 532 (CCPA 1982); *In re Siebentritt* 152 USPQ.

With respect to claims 12 and 15, it would have been obvious step to one having ordinary skill in the art to include an anti-coagulant in the container since it is standard operating procedure in blood collection.

#### *Allowable claims*

Claim 11 is allowed.

The following is an examiner's statement of reasons for allowance: The subject matter not found was the step of displacing red blood cells, platelet-rich plasma, and platelet-poor plasma automatically in a centrifuge that facilitates opening the ports in combination with the other steps (or elements) in the claim reciting displacing the cells from the container by moving the plunger and expelling the cells through the tubing attached to the port.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

### *Response to Arguments*

Applicant's arguments filed 4 October 2006 have been fully considered but they are not persuasive. Applicant argues the following: claims 10 and 12 have been amended to depend from claim 4 whereas previously claims 10 and 12 depended from claim 5; claim 11 is rewritten in independent form.

With regard to claims 10 and 12, this argument is not persuasive for the following reasons: claims 4, 5, 10 and 12 were previously rejected on the teachings of the prior art of record, thus the claims as amended are disclosed in the teachings of the prior art of record, therefore the examiner respectfully traverses the Applicants' arguments and maintains the art rejections of the rejected claims.

With regard to claim 11, this argument is persuasive, note *supra*, under heading *Allowable Subject Matter*.

*Conclusion*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginger T. Chapman whose telephone number is (571) 272-4934. The examiner can normally be reached on Monday through Friday 9:30 a.m. to 6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3761

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ginger Chapman  
Examiner, Art Unit 3761  
2/14/07



TATYANA ZALUKAEVA  
SUPERVISORY PRIMARY EXAMINER

